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Docket No.: 65937-0047

Application No.: 10/803,698

**REMARKS**

This amendment is intended to be fully responsive to the non-final Office Action ("Office Action") having a mailing date of August 25, 2006, wherein claims 1-29 were rejected. Claims 1 and 25 have been amended, but no new matter has been added. Therefore, claims 1-29 remain pending in this matter.

For at least the reasons set forth below, all pending claims are believed to be in condition for allowance over the cited prior art. Further, Applicants believe that there are also reasons other than those set forth below why the pending claims are patentable over the cited prior art and reserve the right to set forth those reasons, and to argue for the patentability of the dependent claims not explicitly addressed herein, in future papers.

**Claim Rejections – 35 U.S.C. § 102**

Claims 1–6, 9–14, 17, 21, 25, and 26 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 6,554,779 to Viola et al. ("Viola"). However, Viola fails to teach or suggest several elements of Applicants' claims. Therefore, the foregoing Section 102 rejections should be withdrawn.

**A. The Law**

To anticipate a claim, the reference must teach every element of the claim. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

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**B. Independent Claim 1**

Independent claim 1, as amended, recites in part:

a biopsy device supported by an adapter, wherein the biopsy device comprises a handpiece and a cutting element having an outer cannula hub removably mounted to the handpiece, wherein the cutting element comprises an outer cannula and an inner cannula disposed within the outer cannula and attached to the handpiece, wherein the outer cannula is connected to the outer cannula hub and defines a tissue receiving opening and an inner cannula disposed within the outer cannula and attached to the handpiece, wherein the outer cannula hub allows selective removal of the handpiece and inner cannula from the outer cannula; and

wherein the adapter comprises:

a base;

a cradle moveably mounted to the base such that the cradle may move while attached to the base, and wherein the cradle is configured to rotatably support the handpiece therein, the cradle configured to inhibit axial movement of the handpiece relative to the cradle when locked therein;

an indexing guide moveable with the cradle and including a receptacle within which the outer cannula hub is rotatably received, the indexing guide configured to inhibit rotation and axial movement of the outer cannula hub and outer cannula relative to the indexing guide and the cradle when the outer cannula hub is locked therein.

(Emphasis added). Viola does not show “a cradle moveably mounted to the base such that the cradle may move while attached to the base, and wherein the cradle is configured to rotatably support the handpiece therein,” “an indexing guide moveable with the cradle,” and “the indexing guide configured to inhibit rotation and axial movement of the outer cannula hub and outer cannula relative to the indexing guide and the cradle when the outer cannula hub is locked therein,” as claim 1 recites. Indeed, Viola does not disclose a handpiece. The respective claim elements and arguments directed to the Examiners comments are discussed in detail below.

1) “a cradle moveably mounted to the base and configured to rotatably support the handpiece therein”

Claim 1 recites “a cradle moveably mounted to the base and configured to rotatably support the handpiece therein,” (emphasis added) that Viola does not disclose. Indeed, the cradle rotatably supports the handpiece.

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As described below in detail below in responding to the Examiner's arguments, Applicants note that claim 1 recites "a cradle moveably mounted to the base such that the cradle may move while attached to the base, and wherein the cradle is configured to rotatably support the handpiece therein." Thus, the Examiner's argument that the distal end of the biopsy device is allegedly rotatably supported is not what is claimed. (See the Office Action, Page 3, Last Paragraph—Page 4, Lines 1 and 2). Indeed, as amended, the cradle rotatably supports the handpiece.

However, Viola does not disclose, teach, or even suggest a handpiece. Nor does Viola disclose a moveable cradle configured to rotatably support a handpiece. Indeed, Viola teaches away from both claim elements. The Examiner cited a passage from Viola that does not disclose the claim elements. (See the Office Action of February 28, 2006, Page 2; Viola, Col. 7, Lines 6-21). Viola merely discloses a base 64 (see FIGS. 1, 3) and does not include, as discussed in detail below, "a handpiece," a "cradle moveably mounted to the base" and "configured to rotatably support the handpiece therein." Because Viola does not disclose each and every element of claim 1, claim 1 is patentable over the cited prior art.

a) "a cradle moveably mounted to the base"

Viola does not disclose "a cradle moveably mounted to the base," as claim 1 recites. Indeed, Viola discloses a cradle (near 44) rigidly connected to base 64. (See FIG. 3). The biopsy device (at 66) is received rigidly and non-rotatably by the alleged cradle (near 44). (See FIG. 3).

The Examiner contended that:

Viola et al. teaches of a "moveably mounted cradle to the base" (See Figure 3). Examiner contends that since the cradle is ... capable of being removed from the base, the cradle is "moveably mounted." (See the Office Action, Page 3, Last Paragraph).

Applicants disagree. The Examiner's argument goes to the cradle allegedly being removably mounted. On the contrary, claim 1 recites "a cradle moveably mounted to the base." Thus, as claimed, the cradle is movable *while mounted to the base*. The Examiner's argument goes directly against the claimed "cradle moveably mounted to the base" because the Examiner requires that the cradle be removed from the base. Indeed, the Examiner states that the removal

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of the alleged cradle is somehow equated to the movement claimed by Applicants. However, the Examiner's removal directly contradicts the "movably mounted" language as recited in amended claim 1. Accordingly, Viola does not disclose a movable cradle in any way as positively claimed by Applicants.

Thus, for at least these reasons, claim 1 is in condition for allowance over the cited prior art.

**b) "configured to rotatably support the handpiece"**

Viola also does not show a cradle "configured to rotatably support the handpiece," as amended claim 1 recites. The Examiner contended that:

Viola discloses a "cradle configured to rotatably support a biopsy device" (22), since the distal end of the biopsy device (140 & Column 8, lines 60-64) is fully capable of being rotated in a portion of the cradle (68). Thus, Viola et al. anticipates both a "handpiece" and "moveable cradle configured to rotatably support a biopsy device," as claimed. (See the Office Action, Page 3, Last Paragraph—Page 4, Lines 1 and 2).

Applicants disagree. The Examiner's argument goes to a portion of Viola's alleged biopsy device being rotatably supported. However, as amended, claim 1 recites a cradle "configured to rotatably support the handpiece." As discussed below in detail, amended claim 1 discusses the handpiece and not the biopsy device generally with respect to the claim element including "rotatably support." Thus, the Examiner's argument does not take into account that the handpiece is rotatably supported rather than merely a portion of the biopsy device, e.g., the distal end of the biopsy device. (Viola, FIG. 3, Col. 8, Lines 60-64). Viola clearly discloses a biopsy device 22 that is received (shown by a dashed line) by a knife driver subassembly 44 in base 64. (See FIG. 3). The connection of biopsy device 22 to subassembly 44 is in a non-rotating manner. (See FIG. 3). Further, the connection of biopsy device 22 to base 64 is also in a non-rotating manner. (See FIG. 3).

Thus, because Viola does not disclose a cradle "configured to rotatably support the handpiece," for this separate reason claim 1 is in condition for allowance over the cited prior art.

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c) "handpiece"

As described by claim 1, the biopsy device includes a handpiece. The Examiner contended that:

Viola does teach of a handpiece (the device in its entirety). Examiner contends that since it is fully capable of being held by a human hand it is a "handpiece." (See the Office Action, Page 3, Last Paragraph).

Applicants disagree. The Examiner's argument would lead to any component that is small and light enough to be held in a hand being characterized as a handpiece (e.g., a bolt, a lamp, or a tire). Applicants contend that such an interpretation is against the plain meaning of "handpiece." Even for the sake of argument, no portion of biopsy instrument 22 of Viola is configured for use by a hand (e.g., the hand of a user, operator, or surgeon). Viola discloses a biopsy instrument 22 that is contemplated as a permanent fixture type when installed with base 64. (See Col. 4, Lines 26-28; FIGS. 1 and 3). Such a permanent fixture type device is not configured to be manipulated by one's hand as a "handpiece" but for, only possibly, assembly of the device 20 as a whole. (See FIG. 1). Thus, because Viola does not disclose a "handpiece," claim 1 is in condition for allowance over the cited prior art.

2) "an indexing guide moveable with the cradle"

The Examiner has not shown "an indexing guide moveable with the cradle," as claim 1 recites. (Emphasis added). The Examiner contended that:

Viola et al. does teach of "an indexing guide movable with the cradle" (distal region of 68 & 74) since the "indexing guide" is located on the distal end of the "cradle" and will travel with the cradle. (See the Office Action, Page 4, First Paragraph).

Applicants disagree. As described above, amended claim 1 recites that the cradle is "configured to rotatably support the handpiece." Viola discloses a cradle (near 44) being rigidly connected to base 64. (See FIG. 3). The biopsy device (at 66) is received rigidly and non-rotatably by the cradle (near 44). (See FIG. 3). The alleged indexing guide (distal region of 68

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& 74) is movable separately from the cradle of Viola. (See FIG. 3). Thus, the Examiner shows Viola disclosing an indexing guide that teaches away from the claimed indexing guide at least because Viola's indexing guide is not movable with the cradle (near 44). (See FIG. 3).

Thus, because Viola does not disclose "an indexing guide moveable with the cradle," claim 1 is in condition for allowance over the cited prior art.

**3) "the indexing guide configured to inhibit rotation and axial movement of the outer cannula hub and outer cannula relative to the indexing guide and the cradle when the outer cannula hub is locked therein"**

Moreover, the Examiner has not shown "the indexing guide configured to inhibit rotation and axial movement of the outer cannula hub and outer cannula relative to the indexing guide and the cradle when the outer cannula hub is locked therein." (Emphasis added). The Examiner contended that:

[T]he gravitational and frictional forces will inherently inhibit the rotation and axial movement of the outer cannula hub, until an external force is applied. (See the Office Action, Page 4, First Paragraph).

Applicants disagree. The Examiner's argument would lead to any structure having touching contact as being configured to inhibit movement. Moreover, in the art of biopsy devices, many components are connected together and are not floating in free air (e.g., subject only to the will of gravity). Indeed, the precision desired for biopsy devices requires proper registration of components and thus, some components are in touching contact. However, as is the case with biopsy devices, there are also moving parts. Applicants contend that an external force is inherent to the operation of a biopsy instrument.

Claim 1 recites in part "the indexing guide configured to inhibit rotation and axial movement of the outer cannula hub and outer cannula." However, as the Examiner points out, the alleged indexing guide from Viola is at the distal region of 68 and 74. Thus, the alleged indexing guide shown by Viola is not configured at least to inhibit rotational movement. (See the Office Action, Page 4, Second Paragraph; Viola, FIG. 3). Indeed, the alleged indexing guide appears to freely allow for rotation of a portion 140 of the biopsy device (near 74). (See Viola, FIG. 2). Viola's slide block 74 does not appear to inhibit rotation of the outer cannula. (See

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FIG. 3). Moreover, the Examiner has not shown where Viola discloses the inhibition of rotation "when the outer cannula hub is locked therein," as claim 1 recites.

Thus, at least because Viola does not disclose each and every element of claim 1, claim 1 is in condition for allowance over the cited prior art.

**C. Dependent Claims 2-8 and 17-20**

Claims 2-8 and 17-20 depend from claim 1. Thus, for at least the same reasons as claim 1, claims 2-8 and 17-20 are also in condition for allowance over the cited prior art. Moreover, the dependent claims include independently patentable elements as shown below by way of example.

**1) Dependent Claim 2**

Claim 2 recites in part "wherein the indexing guide includes at least one guide lock that is selectively engagable with the outer cannula hub to inhibit rotation and axial movement thereof." (Emphasis added). The Examiner contended that:

Viola et al. teaches of "guide locks" (76) "selectively engagable with the outer cannula hub" since they can be engaged with the outer cannula hub in order to move the biopsy device or the "guide locks" (76) can remain undisturbed in order to inhibit movement of the biopsy device. (See the Office Action, Page 4, Second Paragraph).

Applicants disagree. The alleged guide locks of Viola are not at least "selectively engagable with the outer cannula hub" as claim 2 recites. Indeed, Viola's alleged guide locks (76) do not show disengaged and engaged position. Thus, it appears that Viola's alleged guide locks are always engaged. The Examiner's argument is apparently directed to the selective movability of the guide locks rather than "selectively engagable" as claimed. Viola does not teach a guide lock as claimed and, moreover, does not teach a guide lock that is "selectively engagable with the outer cannula hub" because Viola's alleged guide locks (76) are always engaged. Thus, claim 2 is independently patentable over the cited prior art.

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**2) Dependent Claim 3**

Claim 3 recites "wherein the indexing guide includes two guide locks." The Examiner cites that Viola includes indexing knobs 76. However, as discussed above with respect to claim 2, the indexing knobs are not "guide locks." (See FIG. 3). Thus, claim 3 is independently patentable over the cited prior art.

**3) Dependent Claim 5**

Claim 5 recites "wherein the outer cannula hub includes at least one notch and the guide lock is configured to be received in the notch to prevent movement of the outer cannula hub in a first axial direction." The Examiner cited Viola including "between 74 & 76" as allegedly anticipating claim 5. (See the Office Action, Page 3; Viola, FIG. 3). Moreover, the Examiner contended that:

Viola et al. discloses an "outer cannula hub" (38 to 28) with "a notch to prevent movement" (the gap between 140 and 41). Examiner contends if the "notch" is resting in the "indexing guide" (distal end of 68), then the "notch" prevents the biopsy device from moving. (See the Office Action, Page 4, Last Paragraph).

Applicants disagree at least because the Examiner has previously identified Viola's alleged guide lock (76) and is now alleging different elements of Viola where "the guide lock is configured to be received in the notch," as claim 5 recites. (See "guide lock" in the Office Action, Page 4, Second Full Paragraph).



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**4) Dependent Claim 17**

Claim 17 recites "wherein said cradle provides for rotational positioning of the tissue receiving opening." The Examiner contended that:

[T]he cradle (68) is fully capable of "rotational positioning" of the proximal end of the biopsy device. (See the Office Action, Page 5, First Paragraph).

Applicants disagree at least because the Examiner has identified only the proximal end of the biopsy device as being capable of rotational positioning. Viola does not disclose that "said cradle provides for rotational positioning." Additionally, discussed above, the alleged cradle (68) is not "a cradle moveably mounted to the base," as recited in claim 1, from which claim 17 depends. Thus, claim 17 is independently patentable over the cited prior art.

**D. Independent Claim 9**

Independent claim 9 recites in part:

a base;  
a cradle moveably mounted to the base; and  
an indexing guide moveable with the cradle and including a receptacle within which a portion of the medical instrument is received, the indexing guide configured to inhibit rotation and axial movement of the portion of the medical instrument received in the receptacle relative to the indexing guide and the cradle when the medical instrument is locked therein. (Emphasis added).

As discussed generally above with respect to claim 1, Viola does not disclose "an indexing guide moveable with the cradle," "the indexing guide configured to inhibit rotation and axial movement of the portion of the medical instrument received [...] when the medical instrument is locked therein." Thus, because Viola does not disclose each and every element of claim 9, claim 9 is in condition for allowance over the cited prior art.

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**E. Dependent Claims 10-15 and 21-24**

Dependent claims 10-15 and 21-24 depend from claim 9. Thus, for at least the same reasons as claim 9, claims 10-15 and 21-24 are in condition for allowance over the cited prior art. Moreover, dependent claims 10-15 and 21-24 contain independently patentable elements similar to those discussed above with respect to claims 2-8 and 17-20. Thus, for at least the same reasons argued above with respect to claims 2-8 and 17-20, claims 10-15 and 21-24 are also patentable.

**F. Independent Claim 25**

Independent claim 25 recites in part:

a biopsy device supported by an adapter, wherein the biopsy device comprises a handpiece and a cutting element having an outer cannula hub, wherein the cutting element comprises an outer cannula connected to the outer cannula hub and defining a tissue receiving opening and an inner cannula disposed within the outer cannula and attached to the handpiece; and  
wherein the adapter comprises:  
a base; and  
a cradle moveably mounted to the base such that the cradle may move while attached to the base, and wherein the cradle is configured to rotatably support the handpiece therein and allowing for rotational positioning of the tissue receiving opening, the cradle configured to inhibit axial movement of the handpiece relative to the cradle when locked therein. (Emphasis added).

As discussed generally above with respect to claim 1, Viola does not disclose “a cradle moveably mounted to the base,” “such that the cradle may move while attached to the base,” and “configured to rotatably support the handpiece therein.” An additional independently patentable element includes “allowing for rotational positioning of the tissue receiving opening.” Viola teaches an outer cannula 34 that is rotated (shown as rotation E). (See FIGS. 10 and 13). However, Viola does not teach a tissue receiving opening. At best, Viola discusses a “basket” 32 that is not shown in the drawings. (See Col. 6, Lines 21-24). Thus, because Viola does not teach each and every element of claim 25, claim 25 is in condition for allowance over the cited prior art.

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**G. Dependent Claims 26-29**

Dependent claims 26-29 depend from claim 25. Thus, for at least the same reasons as claim 25, claims 26-29 are in condition for allowance over the cited prior art. Moreover, dependent claims 26-29 contain independently patentable elements similar to those discussed above with respect to claims 17-20. Thus, for at least the same reasons argued above with respect to claims 17-20, claims 26-29 are patentable over the cited prior art.

**Claim Rejections – 35 U.S.C. § 103**

Claims 7, 15, 18-20, and 22-24 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Viola in view of U.S. Publication No. 2004/0077972 to Tsonton et al. ("Tson-ton"). Claims 8 and 16 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Viola in view of U.S. Patent No. 6,551,253 to Worm et al. ("Worm").

**A. The Law**

MPEP § 2143 sets forth the basic requirements for the Patent and Trademark Office to establish prima facie obviousness as follows: "To establish a prima facie case of obviousness, three criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." See MPEP § 2143.

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**B. Dependent Claims 7, 15, 18-20, and 22-24**

Claim 7 recites in part:

wherein the cradle includes a pivotable clamp that is selectively engagable with the handpiece to inhibit rotation and axial movement thereof.

The Examiner contended that:

Tsonton et al. discloses a device with a pivotable clamp ([0097] & Figure 5). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Tsonton et al. to incorporate a pivotable clamp with Viola et al. in order to prevent movement of an object [0118]. (See the Office Action, Page 2, Last Paragraph through Page 3, Lines 1 and 2).

Applicants disagree. Tsonton does not contemplate a clamp "that is selectively engagable with the handpiece," as claim 7 recites. (See Tsonton, Paragraph [0097]). Viola does not discuss the handpiece as claimed. Moreover, the Examiner's motivation does not take into account the complexities of a biopsy device and the structure claimed. Thus, there is no suggestion or motivation to combine Tsonton and Viola other than the Examiner's non-specific reasoning "to prevent movement of an object." (See the Office Action, Page 2, Last Paragraph through Page 3, Lines 1 and 2). Moreover, there is no likelihood of success as Tsonton is configured to lock a shaft 372 rather than a handpiece. (See Tsonton, FIG. 25, Paragraph [0097]). If the clamp contemplated in Tsonton is used to clamp a handpiece, it is likely the handpiece would be damaged. Additionally, as discussed above with respect to claim 1, Viola does not disclose the handpiece. As such, the combination of Tsonton and Viola does not disclose each and every element of the claim. For at least these reasons, claim 7 is in condition for allowance.

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Moreover, claims 15, 18-20, and 22-24 are not specifically addressed in the rejection. The claims further include independently patentable elements. By way of example, claim 29 recites "a clamp selectively positionable to stabilize the biopsy device during a medical procedure." Claim 30 recites a "clamp selectively positionable to allow or inhibit movement of the biopsy device." Claim 31 recites "wherein said clamp engages an outer surface of the biopsy device to inhibit rotation." Thus, unless each and every claim element is specifically addressed, the rejections should be withdrawn.

**C. Dependent Claims 8 and 16**

Claims 8 and 16 recite in part:

a deployment mechanism configured to move the cradle relative to the base.

The Examiner contended that:

Worm et al., however, teaches of a deployment system (26). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Worm et al. to incorporate a deployment system with Viola et al. in order to advance the biopsy device. (See the Office Action, Page 3, Second Paragraph).

Applicants disagree. Worm does not contemplate the cradle or the base, as claimed. Nor does Viola disclose all of the elements as claimed. (See the detailed arguments above with respect to claim 1). Without the elements as claimed, there can be no suggestion or motivation to combine Worm and Viola. Moreover, without the structure of claims 1 and 9 being described, there is no likelihood of success to combine the alleged deployment mechanism (26) of Worm with Viola to arrive at the elements of claims 8 and 16. Indeed, the combination of Worm and Viola does not disclose each and every element of the claims. For at least these reasons, claims 8 and 16 are in condition for allowance.

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CONCLUSION

All rejections have been addressed. In view of the above, the pending claims are believed to be in condition for allowance over the cited prior art. Accordingly, reconsideration and allowance are respectfully requested and the Examiner is respectfully requested to pass this application to issue. It is believed that any fees associated with the filing of this paper are identified in an accompanying transmittal. However, if any additional fees are required, they may be charged to Deposit Account 18-0013, under Order No. 65937-0047 from which the undersigned is authorized to draw. To the extent necessary, a petition for extension of time under 37 C.F.R. 1.136(a) is hereby made, the fee for which should be charged against the aforementioned account.

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Respectfully submitted,

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Amendment (19 pages)